

GWG Review of Clinical Program Applications

Gil Sambrano

Director of Portfolio Development and Review

Clinical Stage Programs

CLINICAL STAGE







CLIN 2



CLIN 3



Scoring System for 2.0 Applications

Score of "1"

Exceptional merit and warrants funding.

Score of "2"

Needs improvement and does not warrant funding at this time but could be resubmitted to address areas for improvement.

Score of "3"

Sufficiently flawed that it does not warrant funding and the same project should not be resubmitted **for at least 6 months**.

Applications are scored by all scientific members of the GWG with no conflict.



CLIN2-08839: Clinical Trial of New Device Configurations for Diabetes Therapy

Therapy: Human embryonic stem cell (hESC)-derived pancreatic progenitor cells delivered in an encapsulation device

Indication: Type 1 diabetes

Goal: Test different configurations of an empty encapsulation device in patients to optimize for use in a combination product with hESC-derived pancreatic progenitor cells.

Major Proposed Activities:

- Manufacture and quality control of different configurations of encapsulation device
- Enroll subjects in the clinical trial
- Analyze clinical data

Funds Requested: \$2,582,074 (\$1,207,799 Co-funding)



CLIN2-08839: Clinical Trial of New Device Configurations for Diabetes Therapy

Budget Review: Pass

GWG Score: 1* Exceptional merit, warrants funding

- Votes for score of 1: 5
- Votes for score of 2: 5
- Votes for score of 3: 1

*Vote by GWG to assign a score of "1": 9 (yes), 8 (no), 1 (abstention)

CIRM Team Recommendation: Do not fund, but allow revision and immediate resubmission for GWG evaluation

